TITLE: LIVER TRANSPLANTATION

EFFECTIVE DATE: April 23, 2018

This policy was developed with input from specialists in endocrinology, gastroenterology, and transplant surgery, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY
These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE
To promote consistency between reviewers in utilization management decision-making by providing the criteria that determine the medical necessity of liver transplantation. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND
Definitions
A. Deceased donor liver transplant is a procedure in which a liver of a deceased individual is removed and transplanted into a different individual. There are currently three different categories of deceased donors: deceased brain death (DBD) donors, deceased cardiac death (DCD) donors, and expanded criteria donors (ECD). The decision for the use of these organs is left to the transplant institution and the organ recipient.
B. Liver transplantation is performed in individuals who have end-stage liver disease to replace a diseased liver with a healthy liver graft from a donor.
C. Living donor liver transplant is a procedure in which part of the liver from a healthy individual is removed and transplanted into a recipient.
D. The Model for End Stage Liver Disease (MELD) score determines priority status on the UNOS waiting list for adult individuals. It is based on objective medical data that reflect an individual’s risk of dying while waiting for a liver transplant. The MELD score is based on bilirubin, International Normalized Ratio (INR), and creatinine.
E. Priority status for candidates under the age of 18 is based on the Pediatric End Stage Liver Disease (PELD) score. This system is similar to the MELD, but recognizes the specific needs of children, including growth failure and age when listed.
F. Reduced-size liver transplant predominantly benefits pediatric individuals but may apply in some adult individuals. Usually, a portion of the adult liver is cut adequately to fit the small individual’s needs and is implanted.
G. Split-liver transplant is a procedure in which a deceased donor liver is split into two grafts; each lobe maintains its vascular and biliary pedicles, which are transplanted along with the graft.
H. Substance use disorder, as defined by the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) is a problematic pattern of use of an intoxicating substance leading to clinically significant impairment or distress. The symptoms associated with a substance use disorder fall into four major groupings: impaired control, social impairment, risky use, and pharmacological criteria (i.e., tolerance and withdrawal).
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I. **Transplant** or **graft** is a portion of the body or a complete organ removed from its natural site and transferred to a separate site in the same or different individual.

J. Transplant **evaluation** is a physical and psychosocial exam to determine if an individual is an acceptable candidate for transplantation. The specific exams and tests depend on the individual’s diagnosis and health history and vary from hospital to hospital. Tests may include the following: cardiac evaluation; lung function tests; lab tests, including blood typing, chemistry panels, and serology testing for hepatitis, HIV and other common viruses; appropriate cancer surveillance, as indicated (e.g., colonoscopy, pap smear, mammogram, prostate cancer screening); dental evaluation with treatment of existing problems; and psychosocial evaluation. Additional testing or clearance may be required to address other significant coexisting medical conditions.

BENEFIT CONSIDERATIONS

1. Prior authorization is **required** for:
   - Liver Transplant **Evaluation**
   - Liver **Transplantation**
   - Please see the prior authorization list for product specific prior authorization requirements.

2. Coverage may vary according to the terms of the member’s plan document.

3. Medica has entered into separate contracts with designated facilities to provide transplant-related health services, as described in the member’s plan document.

4. Complex cases require medical director, external review and, as necessary, discussion with the individual’s physician.

5. Underlying co-morbidity that significantly alters risk/benefit of transplant may preclude transplant eligibility.

6. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.

7. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA

I. Indications for Liver Transplant **Evaluation** [NOTE: For multiorgan transplant, the individual must meet criteria for each organ. Please refer to applicable Medica UM policy.]

   A. Documentation in the medical records indicates that the individual meets **all of the following** criteria:
      1. The individual has End-Stage Liver Disease (ESLD) defined as **one of the following**:
         a. Anticipated life expectancy less than 12-24 months without transplantation
         b. Life-threatening complications that threaten the duration and/or quality of life
         c. Severe liver associated debility frequently associated with sustained portal hypertension.
      2. The individual has **one of the following** conditions:
         a. Cirrhosis
            1) Alcoholic liver disease
            2) Primary biliary cirrhosis
            3) Secondary biliary cirrhosis due to Caroli’s cyst, choledochal cyst, or trauma
            4) Biliary atresia
            5) Primary sclerosing cholangitis
            6) Cystic fibrosis with reduced pulmonary function, defined as having an FEV1 less than 40%
            7) Cryptogenic and postnecrotic cirrhosis
         b. Hepatitis
            1) Post-acute viral infection, including hepatitis A, B, or C causing acute atrophy or post necrotic cirrhosis
            2) Post drug or other toxicity
            3) Chronic active autoimmune hepatitis with cirrhosis
         c. Vascular Disease
            1) Veno-occlusive hepatic disease
            2) Budd-Chiari syndrome
         d. Metabolic and inherited diseases
            1) Alpha-1 antitrypsin deficiency
            2) Wilson’s disease

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3) Protoporphyria
4) Tyrosinemia
5) Hemochromatosis
6) Glycogen storage disease, Types I and IV
7) Crigler-Najjar disease, Type I
8) Familial hypercholesterolemia
9) Hyperoxaluria, Type I (oxalosis)
10) Familial cholestasis
   (i) Byler's syndrome
   (ii) Alagille's syndrome
11) Congenital hepatic fibrosis
12) Non-alcoholic steatohepatitis (NASH)/Non-alcoholic fatty liver disease (NAFLD)

e. Malignancies
1) Unresectable hepatoblastoma confined to the liver
2) Unresectable primary hepatocellular carcinoma (HCC) confined to the liver
3) Unresectable hilar cholangiocarcinoma (CCA)
4) Metastatic neuroendocrine tumors with metastasis confined to the liver
5) Epithelial hemangioendotheliomas (EHE)

f. Miscellaneous
1) Trauma
2) Fulminant hepatic failure
3) Hepatorenal syndrome reversible by transplant
4) Polycystic disease of the liver
5) Familial amyloid polyneuropathy (FAP)
6) Urea cycle defects
7) Hepatopulmonary Syndrome (HPS).

II. Indications for Liver Transplantation
Whole or partial liver transplants using deceased or living donors are considered medically necessary when documentation in the medical record indicates that all of the following criteria are met:
A. Individual meets the institution's eligibility criteria for transplant.
B. Individual meets the criteria in Section I
C. Individual or guardian is able to give informed consent. Individual/guardian and family/social support system are able to comply with the treatment regimen and the necessary follow-up. Inadequate funding to pay for immunosuppressive medications post-transplant is addressed and resolved.
D. For individuals with a recent (24 months) history of substance use disorder, successful completion of a chemical dependency program and 6 months of documented ongoing abstinence.
E. No documented contraindications present as indicated by all of the following:
   1. No uncorrectable non-hepatic medical condition that would itself significantly shorten life expectancy or make transplant success unlikely
   2. No active systemic or localized infection
   3. No active untreated or untreatable non-hepatic malignancy (NOTE: Individuals with underlying malignancy may require oncology consult to assess prognosis and risk of recurrence)
   4. No metastatic (extra-hepatic) liver cancer
   5. No irreversible multisystem organ failure
   6. No HIV infection with detectable viral load and CD4 counts less than 200, acquired immunodeficiency syndrome (AIDS) or history of an AIDS-defining condition that is progressive or recurrent (See Appendix 1)
   7. No active substance use disorder
   8. No irreversible severe brain damage
   9. No limited irreversible rehabilitative potential
   10. No post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by negative PET scan and resolved adenopathy on CT/MRI
   11. No ongoing pattern of noncompliance, psychiatric illness, psychological condition, or limited cognitive ability that would make compliance with a disciplined medical regimen impossible
   12. No lack of psychosocial support as indicated by either no identified caregiver or an uncommitted caregiver
   13. No inability to obtain informed consent from individual or guardian.
III. Indications for Liver Retransplantation

Documentation in the medical records indicates that all of the following criteria are met:
A. Failed previous liver transplantation
B. All of the criteria in Section II are met
C. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant.

CENTERs FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp

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References:

Pre-06/2016 MPC


02/2017 MPC

02/2018 MPC:
APPENDIX 1 – AIDS-Defining Conditions

- Bacterial infections, multiple or recurrent*
- Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus
- Cervical cancer, invasive†
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (greater than 1 month’s duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age greater than 1 month
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy attributed to HIV§
- Herpes simplex: chronic ulcers (greater than 1 month’s duration) or bronchitis, pneumonitis, or esophagitis (onset at age greater than 1 month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (greater than 1 month’s duration)
- Kaposi sarcoma
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Mycobacterium avium complex or Mycobacterium kansasii, disseminated or extrapulmonary
- Mycobacterium tuberculosis of any site, pulmonary†, disseminated, or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis jirovecii (previously known as “Pneumocystis carinii”) pneumonia
- Pneumonia, recurrent†
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain, onset at age greater than 1 month
- Wasting syndrome attributed to HIV§

* Only among children aged less than 6 years.
† Only among adults, adolescents, and children aged greater than or equal to 6 years.
§ Suggested diagnostic criteria for these illnesses, which might be particularly important for HIV encephalopathy and HIV wasting syndrome, are described in the following references:
  - CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43(No. RR-12).
  - CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(No. RR-17).